REMARKS

Upon entry of the amendment, claims 21-38, 40-46, 48-54, 56, 57 and 63-66 will be pending in the application. New claims 63-65 are supported in e.g, current claims 21, 22 and 37. have been added. No new matter is added.

Rejections under 35 U.S.C. §103(a)

Claims 21-38, 40-46, 48-54, 56, 57 and 63 remain rejected as unpatentable over U.S. Patent No. 5,858,410 ("Muller") and U.S. Patent No. 5,739,152 ("Andersson"). The rejection is traversed to the extent it is applied to the claims as amended.

Independent claims 21, 22, and 38 have been amended to require that the particle size of the recited particle is smaller following autoclaving as compared to the size of a particle following autoclaving that consists essentially of the biologically active substance or drug and phospholipid surface modifier without said thermoprotecing agent. The specification explains that this newly added feature was unexpected. Applicants teach in the specification: at page 2, second full paragraph:

> Surprisingly, it was found that selected compositions of submicron- to micron-sized particulate suspension of water-insoluble or poorly water-soluble pharmaceutical agents containing a pharmaceutically acceptable water soluble polyhydroxy compound could be autoclaved without any marked increase of mean particle size.

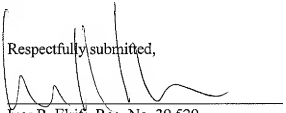
There is no suggestion of this feature in the combination of Muller and Andersson. Muller is cited for teaching nanosuspensions comprising 0.001-30% lecithin and the compounds polyvinyl alcohol, poloxamer, glucose, mannose trehalose, and sorbitol at 0.1-2% and at 0.1-

30%; as well as, disclosing parental, intramuscular and subcutaneous administration, active ingredients such as cyclosporine and autoclaving. However, Muller lacks any teaching or suggestion that a thermoprotecting agent confers resistance to particle size increase following autoclaving. Andersson does not cure the deficiencies of Muller as Andersson is also silent about the protective effect of a thermoprotecting agent now required by the claims.

Accordingly, claims 21-38, 40-46, 48-54, 56, 57 and 63 are non-obvious over the combination of Muller and Andersson.

New claims 64-66 are further patentable over the combination of Muller and Andersson because the claims encompass only compositions that *consist of* the recited biologically active substance (claims 64 and 66) or drug (claim 65), phospholipid surface modifiers, and thermoprotecting agent. There is no suggestion in these references alone or in combination of compositions with only these components.

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Should any questions arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below. A petition for an extension of time accompanies this response. With this Petition a response is believed due on or before November 30, 2009 (November 28, 2009 being a Saturday). Please charge any additional fees due, or credit any overpayment of same, to Deposit Account 50-0311 (Ref.: 28069-503001US).



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Date: November 30, 2009